

## Checklist for ACUC Incident Investigation

1. The ACUC Chair receives notification of issue/incident.
2. The Chair initiates appropriate steps to validate the real or potential seriousness of the issue/allegation and documents for the record the time and date of notification, who notified the Chair, and who else was notified.

Reportable incidents include:

- a) conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals;
- b) conduct of animal-related activities without appropriate ACUC review and approval;
- c) failure to adhere to ACUC-approved protocols;
- d) implementation of any significant change to ACUC-approved protocols without prior ACUC approval;
- e) conduct of animal-related activities beyond the expiration date established by the ACUC;
- f) chronic failure to provide space for animals in accordance with recommendations of the Guide;
- g) participation in animal-related activities by individuals who have not been appropriately trained;
- h) failure to monitor animals post-procedurally as necessary to ensure well-being;
- i) failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry);
- j) failure to ensure death of animals after euthanasia procedures;
- k) failure of animal care and use personnel to carry out veterinary orders (e.g., treatments);
- l) conduct of official ACUC business requiring a quorum in the absence of a quorum;
- m) conduct of official ACUC business during a period of time that the Committee is improperly constituted;
- n) failure to correct deficiencies identified during the semiannual evaluation in a timely manner;
- o) ACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to noncompliance with the Policy, Animal Welfare Act, the Guide, or the NIH IRP Animal Welfare Assurance.

See "Guidance on Prompt Reporting to OLAW" for additional details on reportable incidents at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>.

3. If the issue/incident was initiated by the NIH ARAC Ombudsman, the guidance provided in the ARAC Guideline should be followed:  
<http://oacu.od.nih.gov/ARAC/ombdsmn.pdf>.
4. The Office of Animal Care and Use (OACU) should be notified as soon as the Chair has determined a reportable incident has occurred. OACU may render an opinion upon receiving the Chair's initial report whether the issue/allegation appears to be an incident that should be reported to the Office of Laboratory Animal Welfare (OLAW).
5. If appropriate, the Chair appoints an investigative agent or subcommittee from the ACUC membership to investigate the issue/allegation.
6. If the issue/incident occurred in a shared or central facility, the guidance provided in the following ARAC Guideline should be followed:  
[http://oacu.od.nih.gov/ARAC/IC\\_Collaborations.pdf](http://oacu.od.nih.gov/ARAC/IC_Collaborations.pdf).
7. The investigative agent or subcommittee conducts investigation, formulates recommendations, and reports back to the ACUC.
8. At a convened meeting with a quorum present, the ACUC then deliberates the investigative report & associated recommendations, formulates any additional conditions and/or corrective actions, and either:
  - a) awaits further information from the subject of the investigation;
  - b) awaits further information from the investigative body; or
  - c) closes out the investigation and renders a final report.
9. Final reports (destined for reporting to OLAW) should be:
  - a) shared in draft with OACU prior to submission;
  - b) in memorandum format;
  - c) signed by the ACUC Chair;
  - d) addressed to Michael M. Gottesman, M.D., Deputy Director for Intramural Research;
  - e) and **NOT** be Through: OACU in the heading; and
  - f) delivered to the Office of Animal Care and Use (OACU).
10. Attachments may be appended to the final report if their inclusion is integral to informing OLAW of key aspects of the background surrounding the incident and demonstrate the ACUC's conviction that the corrective actions taken preclude a reoccurrence of the incident.
11. Attachments to be appended to the final report may include:
  - a) relevant background/supporting documentation,
  - b) interim reports or
  - c) subcommittee reports, as appropriate.

12. As appropriate, the OACU will prepare correspondence transmitting the IC ACUC report to OLAW.

13. Close-out reports of incidents not destined for reporting to OLAW should be forwarded to OACU, either in memorandum or email format.

14. ACUCs should heed the guidance provided in the policy memorandum from the NIH Institutional Official on May 27, 2005 regarding incident reporting:  
<http://oacu.od.nih.gov/ARAC/CommunConcerns.pdf>.

**Reference/Background:**

OLAW Guidance on Reporting of Noncompliance

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-034.html>

<http://grants.nih.gov/grants/olaw/references/laba02v31n5.htm>

[http://grants.nih.gov/grants/olaw/references/lab\\_animal2003v32n9\\_Silverman.htm#sidebar](http://grants.nih.gov/grants/olaw/references/lab_animal2003v32n9_Silverman.htm#sidebar)

<http://grants.nih.gov/grants/olaw/references/laba95.htm#4>

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